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EXAMINER	
REDDIG, PETER J	
ART UNIT	**PAPER NUMBER**
1642	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
31 DAYS	03/09/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/539,233	COY, JOHANNES	
	Examiner	Art Unit	
	Peter J. Reddig	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 June 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *27-42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *27-42* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Claim 27 links inventions 1-18. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim 27. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP ' 804.01.

Group 1, claim(s) 28-33, 36, and 37, drawn to a method for diagnosis of carcinomas their precursor lesions AND prognosis of disease course comprising a) obtaining a cell containing tissue sample from an individual b) determining the level AND subcellular localization of DNase-X NUCLEIC ACID molecules in the cells of said tissue; c) comparing the level AND subcellular localization of DNase-X NUCLEIC ACID molecules within said sample to the contents within a corresponding control sample, not affected by the disease being tested; d) wherein the diagnosis or prognosis of disease course is predicted from considering a significant

increased level relative to the wild type level of DNase-X NUCLEIC ACID molecule in said tissue sample and/or cellular nuclei as indicative of said disorder or of the prognosis of the disease course.

Group 2, claim(s) 28-33, 36, and 37 drawn to a method for diagnosis of carcinomas and their precursor lesions AND prognosis of disease course comprising a) obtaining a cell containing tissue sample from an individual b) determining THE LEVEL of DNase-X NUCLEIC ACID molecules in the cells of said tissue; c) comparing THE LEVEL of DNase-X NUCLEIC ACID molecules within said sample to the contents within a corresponding control sample, not affected by the disease being tested; d) wherein the diagnosis AND prognosis of disease course is predicted from considering a significant increased level relative to the wild type level of DNase-X NUCLEIC ACID molecule in said tissue sample and/or cellular nuclei as indicative of said disorder or of the prognosis of the disease course.

Group 3, claim(s) 28-33, 36, and 37 drawn to a method for diagnosis of carcinomas and their precursor lesions AND prognosis of disease course comprising a) obtaining a cell containing tissue sample from an individual b) determining the SUBCELLULAR LOCALIZATION of DNase-X NUCLEIC ACID molecules in the cells of said tissue; c) comparing the SUBCELLULAR LOCALIZATION of DNase-X NUCLEIC ACID molecules within said sample to the contents within a corresponding control sample, not affected by the disease being tested; d) wherein the diagnosis AND prognosis of disease course is predicted from considering a significant increased level relative to the wild type level of DNase-X NUCLEIC ACID molecule in said tissue sample and/or cellular nuclei as indicative of said disorder or of the prognosis of the disease course.

Group 4, claim(s) 28-33, 36, and 37 drawn to a method for DIAGNOSIS of carcinomas and their precursor lesions comprising a) obtaining a cell containing tissue sample from an individual b) determining the level AND subcellular localization of DNase-X NUCLEIC ACID molecules in the cells of said tissue; c) comparing the level AND subcellular localization of DNase-X NUCLEIC ACID molecules within said sample to the contents within a corresponding control sample, not affected by the disease being tested; d) wherein the DIAGNOSIS is predicted from considering a significant increased level relative to the wild type level of DNase-X NUCLEIC ACID molecule in said tissue sample and/or cellular nuclei as indicative of said disorder.

Group 5, claim(s) 28-33, 36, and 37 drawn to a method for DIAGNOSIS of carcinomas and their precursor lesions comprising a) obtaining a cell containing tissue sample from an individual b) determining THE LEVEL of DNase-X NUCLEIC ACID molecules in the cells of said tissue; c) comparing THE LEVEL of DNase-X NUCLEIC ACID molecules within said sample to the contents within a corresponding control sample, not affected by the disease being tested; d) wherein the DIAGNOSIS is predicted from considering a significant increased level relative to the wild type level of DNase-X molecule in said tissue sample and/or cellular nuclei as indicative of said disorder.

Group 6, claim(s) 28-33, 36, and 37 drawn to a method for DIAGNOSIS of carcinomas and their precursor lesions comprising a) obtaining a cell containing tissue sample from an individual b) determining the SUBCELLULAR LOCALIZATION of DNase-X NUCLEIC ACID molecules in the cells of said tissue; c) comparing the SUBCELLULAR LOCALIZATION of DNase-X NUCLEIC ACID molecules within said sample to the contents within a corresponding control sample, not affected by the disease being tested; d) wherein the DIAGNOSIS is predicted from considering a significant increased level relative to the wild type level of DNase-X NUCLEIC ACID molecule in said tissue sample and/or cellular nuclei as indicative of said disorder.

Group 7, claim(s) 28-33, 36, and 37 drawn to a method for PROGNOSIS OF DISEASE COURSE comprising a) obtaining a cell containing tissue sample from an individual b) determining the level AND subcellular localization of DNase-X NUCLEIC ACID molecules in the cells of said tissue; c) comparing the level AND subcellular localization of DNase-X NUCLEIC ACID molecules within said sample to the contents within a corresponding control sample, not affected by the disease being tested; d) wherein PROGNOSIS OF DISEASE COURSE is predicted from considering a significant increased level relative to the wild type level of DNase-X NUCLEIC ACID molecule in said tissue sample and/or cellular nuclei as indicative of the PROGNOSIS OF DISEASE COURSE.

Group 8, claim(s) 28-33, 36, and 37 drawn to a method for PROGNOSIS OF DISEASE COURSE comprising a) obtaining a cell containing tissue sample from an individual b) determining THE LEVEL of DNase-X NUCLEIC ACID molecules in the cells of said tissue; c) comparing THE LEVEL of DNase-X NUCLEIC ACID molecules within said sample to the contents within a corresponding control sample, not affected by the disease being tested; d) wherein the PROGNOSIS OF DISEASE COURSE is predicted from considering a significant increased level relative to the wild type level of DNase-X NUCLEIC ACID molecule in said tissue sample and/or cellular nuclei as indicative of the PROGNOSIS OF DISEASE COURSE.

Group 9, claim(s) 28-33, 36, and 37 drawn to a method for PROGNOSIS OF DISEASE COURSE comprising a) obtaining a cell containing tissue sample from an individual b) determining the SUBCELLULAR LOCALIZATION of DNase-X NUCLEIC ACID molecules in the cells of said tissue; c) comparing the SUBCELLULAR LOCALIZATION of DNase-X NUCLEIC ACID molecules within said sample to the contents within a corresponding control sample, not affected by the disease being tested; d) wherein the PROGNOSIS OF DISEASE COURSE is predicted from considering a significant increased level relative to the wild type level of DNase-X NUCLEIC ACID molecule in said tissue sample and/or cellular nuclei as indicative of said disorder or of the PROGNOSIS OF DISEASE COURSE.

Group 10, claim(s) 28-35 drawn to a method for diagnosis of carcinomas their precursor lesions AND prognosis of disease course comprising a) obtaining a cell containing tissue sample from an individual b) determining the level AND subcellular localization of DNase-X PROTEIN molecules in the cells of said tissue; c) comparing the level AND subcellular localization of DNase-X PROTEIN molecules within said sample to the contents within a corresponding control sample, not affected by the disease being tested; d) wherein the diagnosis or prognosis of disease

course is predicted from considering a significant increased level relative to the wild type level of DNase-X PROTEIN molecule in said tissue sample and/or cellular nuclei as indicative of said disorder or of the prognosis of the disease course.

Group 11, claim(s) 28-35 drawn to a method for diagnosis of carcinomas and their precursor lesions AND prognosis of disease course comprising a) obtaining a cell containing tissue sample from an individual b) determining THE LEVEL of DNase-X PROTEIN molecules in the cells of said tissue; c) comparing THE LEVEL of DNase-X PROTEIN molecules within said sample to the contents within a corresponding control sample, not affected by the disease being tested; d) wherein the diagnosis AND prognosis of disease course is predicted from considering a significant increased level relative to the wild type level of DNase-X PROTEIN molecule in said tissue sample and/or cellular nuclei as indicative of said disorder or of the prognosis of the disease course.

Group 12, claim(s) 28-35 drawn to a method for diagnosis of carcinomas and their precursor lesions AND prognosis of disease course comprising a) obtaining a cell containing tissue sample from an individual b) determining the SUBCELLULAR LOCALIZATION of DNase-X PROTEIN molecules in the cells of said tissue; c) comparing the SUBCELLULAR LOCALIZATION of DNase-X PROTEIN molecules within said sample to the contents within a corresponding control sample, not affected by the disease being tested; d) wherein the diagnosis AND prognosis of disease course is predicted from considering a significant increased level relative to the wild type level of DNase-X PROTEIN molecule in said tissue sample and/or cellular nuclei as indicative of said disorder or of the prognosis of the disease course.

Group 13, claim(s) 28-35 drawn to a method for DIAGNOSIS of carcinomas and their precursor lesions comprising a) obtaining a cell containing tissue sample from an individual b) determining the level AND subcellular localization of DNase-X PROTEIN molecules in the cells of said tissue; c) comparing the level AND subcellular localization of DNase-X PROTEIN molecules within said sample to the contents within a corresponding control sample, not affected by the disease being tested; d) wherein the PROTEIN is predicted from considering a significant increased level relative to the wild type level of DNase-X molecule in said tissue sample and/or cellular nuclei as indicative of said disorder.

Group 14, claim(s) 28-35 drawn to a method for DIAGNOSIS of carcinomas and their precursor lesions comprising a) obtaining a cell containing tissue sample from an individual b) determining THE LEVEL of DNase-X PROTEIN molecules in the cells of said tissue; c) comparing THE LEVEL of DNase-X PROTEIN molecules within said sample to the contents within a corresponding control sample, not affected by the disease being tested; d) wherein the DIAGNOSIS is predicted from considering a significant increased level relative to the wild type level of DNase-X PROTEIN molecule in said tissue sample and/or cellular nuclei as indicative of said disorder.

Group 15, claim(s) 28-35 drawn to a method for DIAGNOSIS of carcinomas and their precursor lesions comprising a) obtaining a cell containing tissue sample from an individual b) determining

the SUBCELLULAR LOCALIZATION of DNase-X PROTEIN molecules in the cells of said tissue; c) comparing the SUBCELLULAR LOCALIZATION of DNase-X PROTEIN molecules within said sample to the contents within a corresponding control sample, not affected by the disease being tested; d) wherein the DIAGNOSIS is predicted from considering a significant increased level relative to the wild type level of DNase-X PROTEIN molecule in said tissue sample and/or cellular nuclei as indicative of said disorder.

Group 16, claim(s) 28-35, drawn to a method for PROGNOSIS OF DISEASE COURSE comprising a) obtaining a cell containing tissue sample from an individual b) determining the level AND subcellular localization of DNase-X PROTEIN molecules in the cells of said tissue; c) comparing the level AND subcellular localization of DNase-X PROTEIN molecules within said sample to the contents within a corresponding control sample, not affected by the disease being tested; d) wherein PROGNOSIS OF DISEASE COURSE is predicted from considering a significant increased level relative to the wild type level of DNase-X PROTEIN molecule in said tissue sample and/or cellular nuclei as indicative of the PROGNOSIS OF DISEASE COURSE.

Group 17, claim(s) 28-35, drawn to a method for PROGNOSIS OF DISEASE COURSE comprising a) obtaining a cell containing tissue sample from an individual b) determining THE LEVEL of DNase-X PROTEIN molecules in the cells of said tissue; c) comparing THE LEVEL of DNase-X PROTEIN molecules within said sample to the contents within a corresponding control sample, not affected by the disease being tested; d) wherein the PROGNOSIS OF DISEASE COURSE is predicted from considering a significant increased level relative to the wild type level of DNase-X PROTEIN molecule in said tissue sample and/or cellular nuclei as indicative of the PROGNOSIS OF DISEASE COURSE.

Group 18, claim(s) 28-35, drawn to a method for PROGNOSIS OF DISEASE COURSE comprising a) obtaining a cell containing tissue sample from an individual b) determining the SUBCELLULAR LOCALIZATION of DNase-X PROTEIN molecules in the cells of said tissue; c) comparing the SUBCELLULAR LOCALIZATION of DNase-X PROTEIN molecules within said sample to the contents within a corresponding control sample, not affected by the disease being tested; d) wherein the PROGNOSIS OF DISEASE COURSE is predicted from considering a significant increased level relative to the wild type level of DNase-X PROTEIN molecule in said tissue sample and/or cellular nuclei as indicative of said disorder or of the PROGNOSIS OF DISEASE COURSE.

Group 19, claim(s) 38, 40, 41 and 42, drawn to a probe for cancer, the probe comprising a probe specifically binding to or reacting with DNase-X NUCLEIC ACIDS and being capable of indicating amount and/or concentration and/or localization of DNase-X NUCLEIC ACIDS in a tissue sample or a sample containing cells and/or cell fragments and/or cell nuclei and a Kit/Pharmaceutical composition useful for treating carcinomas and their precursor lesions comprising a DNase X molecule being NUCLEIC ACIDS.

Group 20, claim(s) 38, 40, 41, and 42 drawn to a probe for cancer, the probe comprising a probe specifically binding to or reacting with DNase-X PROTEINS and being capable of indicating

amount and/or concentration and/or localization of DNase-X PROTEINS in a tissue sample or a sample containing cells and/or cell fragments and/or cell nuclei and a Kit/Pharmaceutical composition useful for treating carcinomas and their precursor lesions comprising a binding partner to a DNase X polypeptide.

Group 21, claim(s) 39 drawn to a method of identifying and obtaining a drug candidate for therapy carcinomas and their precursor lesions comprising the following steps: a) contacting a DNase-X POLYPEPTIDE in the presence of components capable of providing a detectable signal in response to DNase-X ACTIVITY with said drug candidate to be screened under conditions to allow DNase-X ACTIVITY and b) detecting presence or absence of a signal or increase of the signal generated from DNase-X activity wherein the presence or increase of the signal is indicative for a putative drug.

Group 22, claim(s) 39 drawn to a method of identifying and obtaining a drug candidate for therapy carcinomas and their precursor lesions comprising the following steps: a) contacting a DNase-X POLYPEPTIDE in the presence of components capable of providing a detectable signal in response to DNase-X CELL PROLIFERATION with said drug candidate to be screened under conditions to allow DNase-X CELL PROLIFERATION and b) detecting presence or absence of a signal or increase of the signal generated from DNase-X cell proliferation wherein the presence or increase of the signal is indicative for a putative drug.

Group 23, claim(s) 39 drawn to a method of identifying and obtaining a drug candidate for therapy carcinomas and their precursor lesions comprising the following steps: a) contacting a DNase-X POLYPEPTIDE in the presence of components capable of providing a detectable signal in response to DNase-X CELL DIFFERENTIATION with said drug candidate to be screened under conditions to allow DNase-X CHANGES IN CELL DIFFERENTIATION and b) detecting presence or absence of a signal or increase of the signal generated from DNase-X cell differentiation, wherein the presence or increase of the signal is indicative for a putative drug.

Group 24, claim(s) 39 drawn to a method of identifying and obtaining a drug candidate for therapy carcinomas and their precursor lesions comprising the following steps: a) contacting a CELL EXPRESSING A DNASE-X POLYPEPTIDE in the presence of components capable of providing a detectable signal in response to DNase-X ACTIVITY with said drug candidate to be screened under conditions to allow DNase-X ACTIVITY and b) detecting presence or absence of a signal or increase of the signal generated from DNase-X activity wherein the presence or increase of the signal is indicative for a putative drug.

Group 25, claim(s) 39 drawn to a method of identifying and obtaining a drug candidate for therapy carcinomas and their precursor lesions comprising the following steps: a) contacting a CELL EXPRESSING A DNASE-X POLYPEPTIDE in the presence of components capable of providing a detectable signal in response to DNase-X CELL PROLIFERATION with said drug candidate to be screened under conditions to allow DNase-X CELL PROLIFERATION and b) detecting presence or absence of a signal or increase of the signal generated from DNase-X cell proliferation wherein the presence or increase of the signal is indicative for a putative drug.

Group 26, claim(s) 39 drawn to a method of identifying and obtaining a drug candidate for therapy carcinomas and their precursor lesions comprising the following steps: a) contacting a CELL EXPRESSING A DNASE-X POLYPEPTIDE in the presence of components capable of providing a detectable signal in response to DNase-X CELL DIFFERENTIATION with said drug candidate to be screened under conditions to allow DNase-X CHANGES IN CELL DIFFERENTIATION and b) detecting presence or absence of a signal or increase of the signal generated from DNase-X cell differentiation, wherein the presence or increase of the signal is indicative for a putative drug.

Group 27, claim(s) 40-42 drawn to a kit/ pharmaceutical composition for the detection and/or treatment of carcinomas and their precursor lesions, comprising a DNase-X POLYPEPTIDE.

Group 28, claim(s) 40-42 drawn to a kit/ pharmaceutical composition for the detection and/or treatment of carcinomas and their precursor lesions, comprising ONE activator/agonist of a DNase-X polypeptide.

Group 29, claim(s) 40-42 drawn to a kit/ pharmaceutical composition for the detection and/or treatment of carcinomas and their precursor lesions, comprising ONE inhibitor/antagonist of a DNase-X polypeptide.

Group 30, claim(s) 40-42 drawn to a kit/ pharmaceutical composition for the detection and/or treatment of carcinomas and their precursor lesions, comprising ONE activator of the expression of a DNase-X polypeptide.

Group 31, claim(s) 40-42 drawn to a kit/ pharmaceutical composition for the detection and/or treatment of carcinomas and their precursor lesions, comprising ONE inhibitor of the expression of a DNase-X polypeptide.

Group 32, claim(s) 40-42 drawn to a kit/ pharmaceutical composition for the detection and/or treatment of carcinomas and their precursor lesions, comprising ONE drug candidate as described in claim 13 (It is assumed that claim 13 is claim 39, clarification is requested).

Group 33, claim(s) 41-42 drawn to a pharmaceutical composition for the treatment of carcinomas and their precursor lesions, comprising MORE THAN ONE activator/agonist of a DNase-X polypeptide.

Group 34, claim(s) 41-42 drawn to a pharmaceutical composition for the treatment of carcinomas and their precursor lesions, comprising MORE THAN ONE inhibitor/antagonist of a DNase-X polypeptide.

Group 35, claim(s) 41-42 drawn to a pharmaceutical composition for treatment of carcinomas and their precursor lesions, comprising MORE THAN ONE activator of the expression of a DNase-X polypeptide.

Group 36, claim(s) 41-42 drawn to a pharmaceutical composition for the treatment of carcinomas and their precursor lesions, comprising MORE THAN ONE inhibitor of the expression of a DNase-X polypeptide.

Group 37, claim(s) 41-42 drawn to a pharmaceutical composition for the treatment of carcinomas and their precursor lesions, comprising MORE THAN ONE drug candidate as described in claim 13 (It is assumed that claim 13 is claim 39, clarification is requested).

Group 38, claim(s) 41-42 drawn to a pharmaceutical composition for the treatment of carcinomas and their precursor lesions, comprising ONE DNase NUCLEIC ACID, other than DNase-X. Applicants must elect and identify ONE DNase NUCLEIC ACID, other than DNase-X.

Group 39, claim(s) 41-42 drawn to pharmaceutical composition for the treatment of carcinomas and their precursor lesions, comprising MORE THAN ONE DNase NUCLEIC ACID. Applicants must elect and identify A SPECIFIC COMBINATION OF DNase NUCLEIC ACIDs.

Group 40, claim(s) 41-42 drawn to a pharmaceutical composition for the treatment of carcinomas and their precursor lesions, comprising ONE DNase POLYPEPTIDE, other than DNase-X. Applicants must elect and identify ONE DNase POLYPEPTIDE, other than DNase-X.

Group 41, claim(s) 41-42 drawn to a pharmaceutical composition for the treatment of carcinomas and their precursor lesions, comprising MORE THAN ONE DNase POLYPEPTIDE. Applicants must elect and identify A SPECIFIC COMBINATION OF DNase POLYPEPTIDES.

Group 42, claim(s) 41-42 drawn to a pharmaceutical composition for the treatment of carcinomas and their precursor lesions, comprising ONE DNase POLYPEPTIDE, other than DNase-X, activator/agonist. Applicants must elect and identify ONE DNase POLYPEPTIDE, other than DNase-X.

Group 43, claim(s) 41-42 drawn to pharmaceutical composition for treatment of carcinomas and their precursor lesions, comprising MORE THAN ONE DNase POLYPEPTIDE activator/agonist. Applicants must elect and identify A SPECIFIC COMBINATION OF DNase POLYPEPTIDES.

Group 44, claim(s) 41-42 drawn to a pharmaceutical composition for the treatment of carcinomas and their precursor lesions, comprising ONE DNase POLYPEPTIDE, other than DNase-X, inhibitor/antagonist. Applicants must elect and identify ONE DNase POLYPEPTIDE, other than DNase-X.

Group 45, claim(s) 41-42 are drawn to a pharmaceutical composition the treatment of carcinomas and their precursor lesions, comprising MORE THAN ONE DNase POLYPEPTIDE inhibitor/antagonist. Applicants must elect and identify A SPECIFIC COMBINATION OF DNase POLYPEPTIDES.

Group 46, claim(s) 41-42 drawn to a pharmaceutical composition for the treatment of carcinomas and their precursor lesions, comprising ONE DNase POLYPEPTIDE, other than DNase-X, binding partner. Applicants must elect and identify ONE DNase POLYPEPTIDE, other than DNase-X.

Group 47, claim(s) 41-42 drawn to a pharmaceutical composition the treatment of carcinomas and their precursor lesions, comprising MORE THAN ONE DNase POLYPEPTIDE binding partner. Applicants must elect and identify A SPECIFIC COMBINATION OF DNase POLYPEPTIDES.

Group 48, claim(s) 41-42 drawn to a pharmaceutical composition for the treatment of carcinomas and their precursor lesions, comprising ONE DNase POLYPEPTIDE, other than DNase-X, drug candidate as described in claim 13 (It is assumed that claim 13 is claim 39, clarification is requested). Applicants must elect and identify ONE DNase POLYPEPTIDE, other than DNase-X.

Group 49, claim(s) 41-42 drawn to a pharmaceutical composition the treatment of carcinomas and their precursor lesions, comprising MORE THAN ONE DNase POLYPEPTIDE drug candidate as described in claim 13 (It is assumed that claim 13 is claim 39, clarification is requested). Applicants must elect and identify A SPECIFIC COMBINATION OF DNase POLYPEPTIDES.

In accordance with the decisions in *In re Harnisch*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and *Ex parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984), restriction of a Markush group is proper where the compounds within the group either (1) do not share a common utility, or (2) do not share a substantial structural feature disclosed as being essential to that utility. In addition, a Markush group may encompass a plurality of independent and distinct inventions where two or more members are so unrelated and diverse that a prior art reference anticipating the claim with respect to one of the members would not render the other member(s) obvious under 35 USC 103. Since the decisions in *In re Weber*, 198 USPQ 328 (CCPA 1978) and *In re Hass*, 198 USPQ 334 (CCPA 1978), it is proper for the Office to refuse to examine that which applicants regard as their invention, if the subject matter in a claim lacks unity of invention, see MPEP 803.02.

(1) Inventions 27 through 49 are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the patentability of the combination does not rely necessarily and solely on the patentability of any one subcombination and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the patentability of the combination does not rely necessarily and solely on the patentability of any one subcombination as clearly evidenced by the plural subcombinations claimed. Further, each of the subcombinations has utility by itself because each of the subcombinations are useful for screening for different variables and different markers. Thus the claims are distinct as required by MPEP 806.05(c).

The inventions listed as Groups 1-49 do not relate to a single general inventive concept under PCT Rule 13.1 because unity of invention between different categories of inventions will only be found to exist if specific combinations of inventions are present. Those combinations include:

A) A product and a special process of manufacture of said product.

B) A product and a process of use of said product.

C) A product, a special process of manufacture of said product, and a process of use of said product.

D) A process and an apparatus specially designed to carry out said process.

E) A product, a special process of manufacture of said product, and an apparatus specially designed to carry out said process.

The inventions of groups 1-49 are drawn to multiple products as well as multiple methods of using those products. Allowed combinations do not include multiple products, and multiple

methods of using said products, as claimed in the instant application. Hence, only one product and one process of use of said product relate to a single general inventive concept. Since multiple products and multiple methods with different special technical features are claimed, the first invention of the category first mentioned in the claims of the application will be considered as the main invention in the claims, see PCT article 17(3) (a) and 1.476 (c), 37 C.F.R. 1.475(d).

Accordingly, Groups 1-49 are not so linked as to form a single general inventive concept and the finding of lack of unity is proper.

Species Elections for Groups 1-18

A. Claim 1 is generic to the following disclosed patentably distinct species of the form of sample:

blood, plasma, serum, liquor, lymph, bone marrow, swabs, washes, lavages, secretions, transsudates, exsudates, sputum, stool, urine, semen, cell- and tissue-samples, punctuates or biopsies

B. Claim 1 is generic to the following disclosed patentably distinct species of the form of carcinoma:

head and the neck, cancer of the respiratory tract, cancer of the gastrointestinal tract, cancer of the skin and its appendages, cancer of the central and peripheral nervous system, cancer of the urinary system, cancer of the reproductive system, cancer of the endocrine system, cancer of the soft tissues and bone, cancer of the lymphopoietic and hematopoietic system, breast cancer, lung cancer, cervical cancer, colorectal cancer or anogenital cancer

Species Elections for Groups 19, 20, and 27-49

A. Claim 41 is generic to the following disclosed patentably distinct species of the form of carcinoma:

head and the neck, cancer of the respiratory tract, cancer of the gastrointestinal tract, cancer of the skin and its appendages, cancer of the central and peripheral nervous system, cancer of the urinary system, cancer of the reproductive system, cancer of the endocrine system, cancer of the soft tissues and bone, cancer of the lymphopoietic and hematopoietic system, breast cancer, anogenital cancer or colorectal cancer

In accordance with the decisions in *In re Harnisch*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and *Ex parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984), restriction of a Markush group is proper where the compounds within the group either (1) do not share a common utility, or (2) do not share a substantial structural feature disclosed as being essential to that utility. In addition, a Markush group may encompass a plurality of independent and distinct inventions where two or more members are so unrelated and diverse that a prior art reference anticipating the claim with respect to one of the members would not render the other member(s) obvious under 35 USC 103. Since the decisions in *In re Weber*, 198 USPQ 328 (CCPA 1978) and *In re Hass*, 198 USPQ 334 (CCPA 1978), it is proper for the Office to refuse to examine that which applicants regard as their invention, if the subject matter in a claim lacks unity of invention, see MPEP 803.02.

The above species are independent or distinct because they comprise structurally distinct molecules and have different modes of operation and different effects. Further, each species would require different searches and the consideration of different patentability issues.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species from each species group above for the elected invention Group, even though this requirement is traversed. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103 of the other invention.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Applicant is advised that the reply to this restriction requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter J. Reddig whose telephone number is (571) 272-9031. The examiner can normally be reached on M-F 8:30 a.m.-5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley can be reached on (571) 272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Peter J. Reddig, Ph.D.
Examiner
Art Unit 1642

PJR

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571) 272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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SUSAN UNGAR, PH.D
PRIMARY EXAMINER

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